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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,651	09/15/2003	Bart De Strooper	2676-6086US	2464
24247	7590	09/12/2005	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			EMCH, GREGORY S	
			ART UNIT	PAPER NUMBER
			1649	
DATE MAILED: 09/12/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/662,651

**Applicant(s)**

STROOPER ET AL.

**Examiner**

Gregory S. Emch

**Art Unit**

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 30,31 and 44-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30,31 and 44-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 15 September 2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Seq. alignments A-E.

## **DETAILED ACTION**

### ***Formal Matters***

Claim 30 was amended and new claims 44-48 were added in the communication dated May 9, 2005. Claims 1-48 are currently pending.

### ***Election/Restrictions***

Applicant's election with traverse of Group VII, claims 30-31, in the communication dated May 9, 2005 is acknowledged. Applicant's argument that all fragments and variants of SEQ ID NO: 7 should be examined, including SEQ ID NOs: 5, 7, 8, 12, and 13 has been fully considered and is found to be partially persuasive. Applicant asserts that it would not be a burden to examine SEQ ID NO: 12, and variants thereof, including SEQ ID NOs: 5, 7, 8, 12, and 13 because a search for SEQ ID NO: 12 would necessarily encompass SEQ ID NOs: 5, 7, 8, 12, and 13. Applicant is only entitled to a search of sequences currently disclosed in the claims; applicant is not entitled to a search for all fragments and variants of SEQ ID NO: 12. Therefore, the restriction requirement will be modified such that SEQ ID NOs: 5, 7, 8, 12, and 13 only are examined. Currently, claims 30-31 and 44-48 drawn to SEQ ID NOs: 5, 7, 8, 12, and 13 are under consideration. Applicant's election of the species B.) type I transmembrane domain proteins and 2.) amyloid precursor protein (APP) is also acknowledged.

***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the European patent Office on March 16, 2001. It is noted, however, that applicant has not filed a certified copy of the 01201015.3 application as required by 35 U.S.C. 119(b).

***Specification***

The disclosure is objected to because of the following informalities: The first line of the specification refers to PCT International Patent Application No.

PCT/EP/02/043033. The correct PCT No. is PCT/EP02/03033.

Appropriate correction is required.

***Information Disclosure Statement***

A signed and initialed copy of the IDS paper filed September 15, 2003 is enclosed in this action.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. §112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The claim is drawn to a compound capable of modulating the interaction between a complex of a presenilin and a type I transmembrane protein, said compound identified by a process comprising: treating said complex or binding domains of said complex with at least one compound; monitoring the interaction of the presenilin and said type I transmembrane protein; and determining whether said at least one compound modulates the interaction between presenilin and said type I transmembrane protein thus identifying a compound capable of modulating said interaction between a complex of a presenilin and a type I transmembrane protein and is thus a genus claim.

According to the specification, (p.16, paragraph 51) the compounds capable of modulating the interaction between a complex of a presenilin and a type I transmembrane protein of the present invention include those molecules listed in Figure 6. Also, according to the specification, (pp.6-7, paragraphs 11-14) said compounds can be any inorganic or organic molecules, peptides, peptido-mimetics, proteins, antibodies, carbohydrates, nucleic acids or derivatives thereof. Further, a compound is disclosed as modulating the interaction if it has an antagonizing or agonizing effect on the interaction.

The specification and claims set forth a multitude of potential molecules encompassed by their invention. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to how to make the claimed compounds. Structural features that could distinguish compounds in the genus from others in the molecular class are missing from the disclosure. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, any compound alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of SEQ ID NOs: 1-13 identified by the recited screening method, does not reasonably provide enablement for any other compound capable of modulating the interaction between a complex of a presenilin and a type I transmembrane protein identified by said screening method.

The claim is drawn to a compound capable of modulating the interaction between a complex of a presenilin and a type I transmembrane protein, said compound identified

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by a process comprising: treating said complex or binding domains of said complex with at least one compound; monitoring the interaction of the presenilin and said type I transmembrane protein; and determining whether said at least one compound modulates the interaction between presenilin and said type I transmembrane protein thus identifying a compound capable of modulating said interaction between a complex of a presenilin and a type I transmembrane protein.

According to the specification, (p.16, paragraph 51) the compounds capable of modulating the interaction between a complex of a presenilin and a type I transmembrane protein of the present invention include those molecules listed in Figure 6. Also, according to the specification, (pp.6-7, paragraphs 11-14) said compounds can be any inorganic or organic molecules, peptides, peptido-mimetics, proteins, antibodies, carbohydrates, nucleic acids or derivatives thereof. Further, a compound is disclosed as modulating the interaction if it has an antagonizing or agonizing effect on the interaction.

The claim is overly broad in the recitation of "a compound" since insufficient guidance is provided as to which of the myriad of molecular species encompassed by the claim will retain the characteristics of modulating the interaction between a complex of a presenilin and a type I transmembrane protein.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. Since detailed information regarding the structural requirements of any compound are lacking, it is unpredictable as to which variations, if any, meet the limitations of the claims. Applicant is required to

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enable one of skill in the art to make the claimed invention, while the claims encompass any compound capable of modulating the interaction between a complex of a presenilin and a type I transmembrane protein, it would require undue experimentation for one of skill in the art to make the claimed products.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31 and 44-48 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,604,131 to Wadsworth et al.

The claims are drawn to a compound capable of modulating the interaction between a complex of a presenilin and a type I membrane protein, wherein said compound is selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, and SEQ ID NO: 10, or wherein said compound comprises SEQ ID NO: 12, or wherein said compound comprises SEQ ID NO: 7, or wherein said compound comprises SEQ ID NO: 5, or wherein said compound comprises SEQ ID NO: 8, or wherein said compound comprises SEQ ID NO: 13. The '131 patent discloses a polypeptide with an amino acid sequence which is 100% identical to Applicant's SEQ ID NOS: 5, thus meeting the



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limitation of claims 31 and 46 (see attached sequence alignment A). The '131 patent also discloses a polypeptide comprising an amino acid sequence which is 100% identical to Applicant's SEQ ID NO: 12, thus meeting the limitation of claim 44.

Although the full-length polypeptide disclosed by Wadsworth is not 100% identical to Applicant's SEQ ID NO: 12; it encompasses SEQ ID NO: 12 (see attached sequence alignment B). The '131 patent also discloses a polypeptide comprising an amino acid sequence which is 100% identical to Applicant's SEQ ID NO: 7, thus meeting the limitation of claim 45. Although the full-length polypeptide disclosed by Wadsworth is not 100% identical to Applicant's SEQ ID NO: 7; it encompasses SEQ ID NO: 7 (see attached sequence alignment C). The '131 patent also discloses a polypeptide comprising an amino acid sequence which is 100% identical to Applicant's SEQ ID NO: 8, thus meeting the limitation of claim 47 (see attached sequence alignment D). The '131 patent also discloses a polypeptide comprising an amino acid sequence which is 100% identical to Applicant's SEQ ID NO: 13, thus meeting the limitation of claim 48. (see attached sequence alignment E). Since the patent discloses all of the elements of the claims, claims 31 and 44-48 are anticipated by US Patent No. 5,604,131 to Wadsworth et al.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

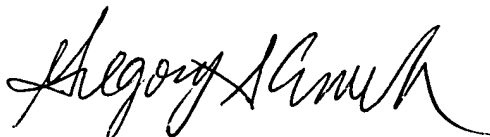
Art Unit: 1649

***Advisory Information***

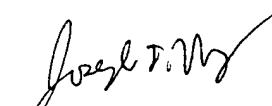
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 8:30AM to 5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gregory S. Emch, Ph. D.  
Patent Examiner  
Art Unit 1649  
August 31, 2005



**JOSEPH MURPHY**  
**PATENT EXAMINER**

Seq. Alignment A

SEQ ID NO: 5

US-08-123-702-45

; Sequence 45, Application US/08123702  
; Patent No. 5604131  
; GENERAL INFORMATION:  
; APPLICANT: Wadsworth, Samuel  
; APPLICANT: Snyder, Benjamin  
; APPLICANT: Reddy, Vermuri, B.  
; APPLICANT: Wei, Chamer  
; TITLE OF INVENTION: A cDNA Genomic Hybrid Sequence Encoding APP770  
; Patent No. 5604131  
; TITLE OF INVENTION: Containing a Genomic DNA Insert of the KI and OX-2 Regions  
; NUMBER OF SEQUENCES: 45  
; CORRESPONDENCE ADDRESS:  
; ADDRESSEE: Patrea L. Pabst  
; STREET: 2800 One Atlantic Center  
; STREET: 1201 West Peachtree Street  
; CITY: Atlanta  
; STATE: GA  
; COUNTRY: USA  
; ZIP: 30309-3450  
; COMPUTER READABLE FORM:  
; MEDIUM TYPE: Floppy disk  
; COMPUTER: IBM PC compatible  
; OPERATING SYSTEM: PC-DOS/MS-DOS  
; SOFTWARE: PatentIn Release #1.0, Version #1.25  
; CURRENT APPLICATION DATA:  
; APPLICATION NUMBER: US/08/123,702  
; FILING DATE: 17-SEPT-1993  
; CLASSIFICATION: 435  
; ATTORNEY/AGENT INFORMATION:  
; NAME: Pabst, Patrea L.  
; REGISTRATION NUMBER: 31,284  
; REFERENCE/DOCKET NUMBER: TSI121  
; TELECOMMUNICATION INFORMATION:  
; TELEPHONE: (404)-873-8794  
; TELEFAX: (404)-873-8795  
; INFORMATION FOR SEQ ID NO: 45:  
; SEQUENCE CHARACTERISTICS:  
; LENGTH: 49 amino acids  
; TYPE: amino acid  
; TOPOLOGY: linear  
; MOLECULE TYPE: protein  
; FEATURE:  
; NAME/KEY: mutation  
; LOCATION: 29  
; OTHER INFORMATION: "Val can be mutated to be Phe"  
US-08-123-702-45

Query Match 100.0%; Score 48; DB 1; Length 49;  
Best Local Similarity 100.0%; Pred. No. 0.046;  
Matches 11; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 TVIVITLVMLK 11  
|||  
Db 26 TVIVITLVMLK 36

Seq. Alignment B

SEQ ID NO: 12

US-08-123-702-45

; Sequence 45, Application US/08123702  
; Patent No. 5604131  
; GENERAL INFORMATION:  
; APPLICANT: Wadsworth, Samuel  
; APPLICANT: Snyder, Benjamin  
; APPLICANT: Reddy, Vermuri, B.  
; APPLICANT: Wei, Chamer  
; TITLE OF INVENTION: A cDNA Genomic Hybrid Sequence Encoding APP770  
; Patent No. 5604131  
; TITLE OF INVENTION: Containing a Genomic DNA Insert of the KI and OX-2 Regions  
; NUMBER OF SEQUENCES: 45  
; CORRESPONDENCE ADDRESS:  
; ADDRESSEE: Patrea L. Pabst  
; STREET: 2800 One Atlantic Center  
; STREET: 1201 West Peachtree Street  
; CITY: Atlanta  
; STATE: GA  
; COUNTRY: USA  
; ZIP: 30309-3450  
; COMPUTER READABLE FORM:  
; MEDIUM TYPE: Floppy disk  
; COMPUTER: IBM PC compatible  
; OPERATING SYSTEM: PC-DOS/MS-DOS  
; SOFTWARE: PatentIn Release #1.0, Version #1.25  
; CURRENT APPLICATION DATA:  
; APPLICATION NUMBER: US/08/123,702  
; FILING DATE: 17-SEPT-1993  
; CLASSIFICATION: 435  
; ATTORNEY/AGENT INFORMATION:  
; NAME: Pabst, Patrea L.  
; REGISTRATION NUMBER: 31,284  
; REFERENCE/DOCKET NUMBER: TSI121  
; TELECOMMUNICATION INFORMATION:  
; TELEPHONE: (404)-873-8794  
; TELEFAX: (404)-873-8795  
; INFORMATION FOR SEQ ID NO: 45:  
; SEQUENCE CHARACTERISTICS:  
; LENGTH: 49 amino acids  
; TYPE: amino acid  
; TOPOLOGY: linear  
; MOLECULE TYPE: protein  
; FEATURE:  
; NAME/KEY: mutation  
; LOCATION: 29  
; OTHER INFORMATION: "Val can be mutated to be Phe"  
US-08-123-702-45

Query Match 45.9%; Score 67; DB 1; Length 49;  
Best Local Similarity 100.0%; Pred. No. 0.0038;  
Matches 15; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 ATVIVITLVMLKKKQ 15  
| | | | | | | | | | | | | | |  
Db 25 ATVIVITLVMLKKKQ 39

Seq. Alignment C

SEQ ID NO: 7

US-08-123-702-45

; Sequence 45, Application US/08123702  
; Patent No. 5604131  
; GENERAL INFORMATION:  
; APPLICANT: Wadsworth, Samuel  
; APPLICANT: Snyder, Benjamin  
; APPLICANT: Reddy, Vermuri, B.  
; APPLICANT: Wei, Chamer  
; TITLE OF INVENTION: A cDNA Genomic Hybrid Sequence Encoding APP770  
; Patent No. 5604131  
; TITLE OF INVENTION: Containing a Genomic DNA Insert of the KI and OX-2 Regions  
; NUMBER OF SEQUENCES: 45  
; CORRESPONDENCE ADDRESS:  
; ADDRESSEE: Patrea L. Pabst  
; STREET: 2800 One Atlantic Center  
; STREET: 1201 West Peachtree Street  
; CITY: Atlanta  
; STATE: GA  
; COUNTRY: USA  
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; CURRENT APPLICATION DATA:  
; APPLICATION NUMBER: US/08/123,702  
; FILING DATE: 17-SEPT-1993  
; CLASSIFICATION: 435  
; ATTORNEY/AGENT INFORMATION:  
; NAME: Pabst, Patrea L.  
; REGISTRATION NUMBER: 31,284  
; REFERENCE/DOCKET NUMBER: TS1121  
; TELECOMMUNICATION INFORMATION:  
; TELEPHONE: (404)-873-8794  
; TELEFAX: (404)-873-8795  
; INFORMATION FOR SEQ ID NO: 45:  
; SEQUENCE CHARACTERISTICS:  
; LENGTH: 49 amino acids  
; TYPE: amino acid  
; TOPOLOGY: linear  
; MOLECULE TYPE: protein  
; FEATURE:  
; NAME/KEY: mutation  
; LOCATION: 29  
; OTHER INFORMATION: "Val can be mutated to be Phe"  
US-08-123-702-45

Query Match 49.4%; Score 79; DB 1; Length 49;  
Best Local Similarity 100.0%; Pred. No. 0.00018;  
Matches 18; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 VVIATVIVITLVMLKKKQ 18  
|||  
Db 22 VVIATVIVITLVMLKKKQ 39

Seq. Alignment D

SEQ ID NO: 8

US-08-123-702-45

; Sequence 45, Application US/08123702  
; Patent No. 5604131  
; GENERAL INFORMATION:  
; APPLICANT: Wadsworth, Samuel  
; APPLICANT: Snyder, Benjamin  
; APPLICANT: Reddy, Vermuri, B.  
; APPLICANT: Wei, Chamer  
; TITLE OF INVENTION: A cDNA Genomic Hybrid Sequence Encoding APP770  
; Patent No. 5604131  
; TITLE OF INVENTION: Containing a Genomic DNA Insert of the KI and OX-2 Regions  
; NUMBER OF SEQUENCES: 45  
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; OTHER INFORMATION: "Val can be mutated to be Phe"  
US-08-123-702-45

Query Match 100.0%; Score 79; DB 1; Length 49;  
Best Local Similarity 100.0%; Pred. No. 1.7e-05;  
Matches 18; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 VVIATVIVITLVMLKKKQ 18  
|||  
Db 22 VVIATVIVITLVMLKKKQ 39

Seq. alignment E

SEQ ID NO: 13

US-08-123-702-45

; Sequence 45, Application US/08123702  
; Patent No. 5604131  
; GENERAL INFORMATION:  
; APPLICANT: Wadsworth, Samuel  
; APPLICANT: Snyder, Benjamin  
; APPLICANT: Reddy, Vermuri, B.  
; APPLICANT: Wei, Chamer  
; TITLE OF INVENTION: A cDNA Genomic Hybrid Sequence Encoding APP770  
; Patent No. 5604131  
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; NUMBER OF SEQUENCES: 45  
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; NAME/KEY: mutation  
; LOCATION: 29  
; OTHER INFORMATION: "Val can be mutated to be Phe"  
US-08-123-702-45

Query Match 100.0%; Score 67; DB 1; Length 49;  
Best Local Similarity 100.0%; Pred. No. 0.00012;  
Matches 15; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 ATVIVITLVMLKKKQ 15  
|||  
Db 25 ATVIVITLVMLKKKQ 39